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## Curacyte receives European Orphan Drug Designation for its PDE-4 inhibitor in Chronic Lymphocytic Leukemia

09-26-2007

Curacyte AG and its wholly owned subsidiary Curacyte Discovery GmbH based in Leipzig announced today that the European Medicines Agency (EMA) has granted an orphan drug designation for Curacyte's phosphodiesterase-4 inhibitor CD 160130 for the treatment of Chronic Lymphocytic Leukemia (CLL). The Committee for Orphan Medicinal Products (COMP) adopted the positive opinion in their meeting on September 11-12 2007.

The EMA's "Orphan Medicinal Product Designation" is designed to encourage sponsors in developing drugs, which may provide "significant benefit" to patients suffering from rare diseases identified as "life-threatening or very serious." Orphan Medicinal Product Designation provides 10 years of potential market exclusivity if the product candidate is approved for marketing in the European Union. Orphan status also provides EMA advice in optimizing the candidate's clinical development through participation in designing the clinical protocol and preparing the marketing authorization application. A drug candidate designated by the EMA as an Orphan Medicinal Product may also qualify the sponsor for a reduction in regulatory fees as well as a European Union-funded research grant.

"The decision of the EMA to grant an orphan drug designation for our lead PDE-4 inhibitor as a potential novel treatment option for patients suffering from Chronic Lymphocytic Leukemia is another important milestone that underlines our capabilities in drug discovery," said Dr. Helmut Giersiefen, CEO of Curacyte. He further stated that "a new CLL treatment based on PDE-4 inhibition could become a valuable option for physicians and patients to combat this life-threatening and disabling disease without dose-limiting side effects associated to standard chemotherapy."

Chronic lymphocytic leukemia is a slow-progression chronic form of leukemia caused by the presence and accumulation of small, abnormal lymphocytes in the blood and bone marrow which interfere with the production of other cells vital for normal functioning of the blood.

A number of recent studies have observed that phosphodiesterase inhibitors induce apoptosis in leukemic cells. This action of the PDE-4 inhibitors that raise intracellular cAMP levels and induce apoptosis in B-CLL cells appears to be selective. Curacyte's structurally unique PDE-4 inhibitor library has produced several compounds of interest with regard to their activities on B-CLL cells *ex vivo*.

Curacyte's lead product is hemoximer (Pyridoxalated Hemoglobin Polyoxyethylene, PHP) which is under development as a scavenger of nitric oxide, the main causative agent responsible for vasodilation and hypotension in shock. Hemoximer has completed Phase II clinical studies in its primary indication, distributive shock and is entering a Phase III study in catecholamine-resistant distributive shock. Hemoximer is also in Phase II clinical development for cardiogenic shock and as an adjunct to high-dose interleukin 2 (IL-2) cancer therapy for patients with metastatic melanoma and renal cell carcinoma. Apart from hemoximer, Curacyte is also developing a first-in-class small molecule protease inhibitor for prevention of blood loss following cardiac surgery. The development candidate is scheduled to enter clinical studies by 2008.

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Source: Curacyte

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**Related Diseases:** [Chronic Lymphocytic Leukemia \(CLL\)](#)

STEM CELL PR  
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**Related Keywords:** [B.Chronic Lymphocytic Leukemia \(B-CLL\)](#)

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**Related Glossary Terms:** [Bone Marrow \(BM\)](#), [Chemotherapy](#), [CLL](#)

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